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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/171,553

02/08/99

GALBRAITH

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HM22/1030

PATENT GROUP
FOLEY HOAG & ELIOT
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BOSTON MA 02109

EXAMINER

SHUKLA, R

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

10/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/171,553

Applicant(s)

GALBRAITH ET AL.

Examiner

Ram R Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 11, 13-16, 18, 26-28, and 31-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) 8-10, 12, 23, 24, 29 and 30 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. Amendment filed 7-24-00 has been entered. It is noted that the instant application is a 371 case wherein the claims originally presented in the PCT were replaced with a substitute set of claims under Article 34. This substituted set of claims was different in that numbering and subject matter recited in corresponding claims were totally different, for example, claim 19 as originally presented was drawn to an antibody whereas the substituted claim 19 was drawn to a polynucleotide and the substituted set of claims had only 30 claims compared to 31 claims originally presented. Afterwards, Applicants filed a pre-amendment (paper #5, filed 2-8-99) wherein claims 6, 7, and 25 were canceled, claims 1-5, 8-24 and 26-30 were amended and new claims 32-33 were added which have improper claim numbers as per 37 CFR 1.126. However, close examination of the pre-amendment (paper #5) indicated that the amendments were not to the claims filed in the substituted set of claims, rather they were to the claims originally presented in the PCT. Accordingly, the pre-amendment (paper #5) was improper and can not be entered. The amendment is improper because it does not indicate additions and deletions to existing claims with underline and brackets or it is not clear what change has been made to the claims (see MPEP 714.22). Applicants have, later in response to restriction requirement in the office action (paper #6), added new claims 34-43, which again have improper claim numbers under 37 CFR 1.126.

For the sake of compact prosecution, the claims amended and submitted in the pre-amendment and those left in the substituted set of claims have been considered as pending in the instant application and examined. In the instant action, claims 1-5, 8, 12, 19-21, 23, 24, and 29-30 submitted in the pre-amendment (filed 2-8-99) and claims 9-10, 17, and 22 submitted in the substituted set of claims (filed under article 34) have been examined. Claims 32-43 filed in the amendment filed on 7-24-00 have been renumbered as claims 31-42, as per 37 CFR 1.126.

The applicants are required to correct the error in the pre-amendment and amendments filed previously (CFR 1.121; see MPEP 714.22) by filing new amendment in correct format and with correct claim numbers.

Election/Restrictions

2. Applicant's election of the invention of group I, claims 1-5, 8-10, 12, 17, 19-24, and 29-30 in Paper No. 7 (filed 7-24-00) is acknowledged. Because applicant did not distinctly and

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specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

1. Claims 11, 13-16, 18, 26-28 and 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.
2. It is noted that claims 29-30 are placed in groups I-IV since they encompass subject matter of all these groups. Accordingly, these claims will be examined to the extent they encompass the elected subject matter.
3. Newly submitted claims 33-42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 33-42 are drawn to a method of producing transgenic animals and transgenic animals so produced, which were not elected for prosecution, as stated above. Accordingly, claims 33-42, being drawn to the invention of the group IV, have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Arrangement of the Specification

5. The specification is not arranged into sections, for example, the specification does not provide reference to related application, does not have a brief description of figures or a brief summary of invention or an abstract, etc. (37 CFR 1.77 and MPEP 601)

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.

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- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Appropriate corrections are required.

The specification is objected because of following informalities regarding nucleotide and amino acid sequences disclosed in and referred to in the disclosure and the claims.

(i) The specification does not refer to nucleotide and amino acid sequences with sequence identifiers in the disclosure and claims. According to 37 CFR 1.821(d), where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority (see MPEP 2422).

(ii) The specification discloses primer sequences, for example, on pages 28, 29, and 32 of the specification, however these sequences have not been included in the sequence listing. If these sequences are corresponding to a region of the sequences already listed in the "Sequence Listing," the specification should identify the location of the primers by SEQ ID NO and the nucleotide residue numbers, else they should be added to the sequence listing.

(iii) Figure 4 describes a specific polynucleotide corresponding to the nucleotides 5260-8210 of the nucleotide sequence disclosed in Figure 3, in terms of nucleotide differences and corresponding amino acid changes in the polypeptide encoded. Consequently, the polynucleotide disclosed in Figure 4 is subject to 37 CFR 1.821-1.825 and must be listed in the "Sequence Listing". To avoid introduction of new matter, the sequence should consist of a

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sequence that is identical to nucleotides 5260-8210 disclosed in Figure 3 except for the nucleotide and amino acid changes indicated in Figure 4.

(iv) Figure 6 discloses a sequence, however, no sequence listing is provided for this sequence.

Applicants are required to clarify above listed issues and submit separate sequence listing for each polynucleotide molecule as required under 37 CFR 1.821-1.825.

6. The disclosure is objected to because of the following informalities: There is no reference to Figure 5 in the specification, although example 10 (see line 13 on page 34) discloses a Figure J.

Appropriate correction is required.

7. The amendment filed (7-24-00) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: The sequence listing submitted discloses SEQ ID NO 9 and 10, however, there is no support for these sequences in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

8. Claims 29 and 30 are objected to because of the following informalities: These claims recite non-elected subject matter. These claims should be amended to reflect the election. Appropriate correction is required.

9. Claims 8-10, 12, 23, 24, 29 and 30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 8-10, 12, 23, 24, 29 and 30 have not been further treated on the merits.

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Double Patenting

10. Applicant is advised that should claim 17 be found allowable, claim 19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 17 and 19 are identical.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-5, 17, and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published December 21, 1999 in the Federal Register, Volume 64, Number 244, page 71427-71440 (also available at www.uspto.gov).

When the claims are analyzed in light of the specification, the instantly claimed polynucleotides encompass those which encode derivatives of the expression products of these polynucleotides as recited in claims 1-4, embodiment (a), however the specification does not provide any description of the term "derivative". It is noted that the term "derivative" has a very broad meaning. Any end product of a biosynthetic pathway would be a derivative of the starting reactant; however, it may not have any functional or characteristic resemblance or relationship with the starting material. Unless there is a description of the characteristic of the end product an artisan will not know whether the end product will retain the function of the starting material. In the instant case, the starting material is a polynucleotide disclosed in Figures 1-4 and their subsequence. It is noted that while the embodiment (b) of these claims recites expression product displaying a physiological or immunological activity, again these terms are also very broad, for example, a physiological activity of a protein may be as a nutrition, as an enzyme etc. The specification does not describe what physiological activity will be considered that would

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characterize the expression products of the claimed polynucleotides. It is noted that derivatives of a polynucleotide can be produced by a variety of methods which would include mutations (addition, substitution, or deletion) and modification of nucleotides or treatment of the polynucleotides that would alter the structure of the polynucleotide and the protein encoded by the new sequence may still have some physiological activity such as a source of nitrogen. However, the new protein may not have the same enzyme activity as the starting protein. Therefore, description of the derivative is essential for the operability of the claimed invention.

While the claims are interpreted to include synthetic and naturally occurring variants of the polynucleotides, the specification does not provide the features essential for the operability of the polynucleotides of Figures 1-4 which should be retained in the variants to consider a new polynucleotide a variant of Figures 1-4. Again, the recitation of the terms, physiological and immunological activity, does not provide this information since these terms themselves are broad and are not described in the specification and their description will be essential for the operability of the claimed invention. Figure 4 lists changes at some nucleotides that result in change in certain amino acids or addition of residues, for example, deletions at 192 or 193 amino acid residue or addition of three residues at residue 206, however, there is not description in the specification which characteristic would determine whether these would be operable or active like the polynucleotide of Figure 3.

Regarding claims 17 and 19-21, it is noted that the applicants do not describe what is the sequence of all the non-PoEv sequences, nor do they describe what characteristics or sequences of the primers are required for these primers and probes to only initiate synthesis from or hybridize to PoEv sequences and not any other sequences. The specification does not describe what sequences disclosed in the sequences disclosed in Figures 1-4 would have been specific to the PoEv sequences. Again, the operability of the inventions of claims 17 and 19-21 depends on these characteristics and descriptions.

This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of polynucleotides besides SEQ ID No 1, 2, and 3 wherein SEQ ID NO 3 encodes the amino acid sequences disclosed in SEQ ID No 4, 5, and 6, at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

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13. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide disclosed in SEQ ID NO 1, 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames of 524, 1194, and 656 amino acids each, does not reasonably provide enablement for any other claimed embodiments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

In the instant case, the specification as filed has described three figures that contain sequence information of polynucleotides. The specification discloses that the cDNA synthesized from porcine retroviral RNA were cloned in a plasmid vector and the sequences of the clones were determined. The specification also teaches that the earlier identified sequence is disclosed in figure 1, followed by the sequence of figure 2 and finally sequence 3 was obtained (see first paragraph on page 4). It is assumed that the polynucleotide sequences disclosed in the figures 1, 2, and 3 represent the sequence of the polynucleotides disclosed in SEQ ID NO 1, 2, and 3 respectively.

The specification further teaches that the polynucleotide sequence of SEQ ID NO 3 has three open reading frames, of 524, 1194, and 656 amino acids each which by sequence homology are the Gag, Pol and Env proteins of the porcine retrovirus. However, from the disclosure of the specification it is unclear whether the sequences disclosed in SEQ ID NO 1 is a smaller fragment of the polynucleotide disclosed in SEQ ID NO 3 or 2 whether it is an

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independent sequence. It is noted that the polynucleotides of SEQ ID NO 2 and 3 differ in size by only 13 nucleotides whereas the polynucleotide of SEQ ID NO 1 has only 3320 nucleotides. On page 22, the specification discloses that the polynucleotides of SEQ ID NO 1 has 100% sequence similarity between 21-2681 and 2972-5653 and over it has 70.5% sequence identity with SEQ ID NO 3. The specification does not teach whether the polypeptides encoded by SEQ ID NO 1 and by 2 and 3 are same and/or how related they are. Furthermore, whether the polypeptides encoded by SEQ ID NO 1 ORF, 924 and 218 amino acids in length would have the activity of Pol and Env proteins encoded by SEQ ID NO 2 and 3. In the absence of any disclosure about the function of these polynucleotides it is not clear whether any of the fragments of SEQ ID NO 1 will encode any protein which would have the physiological activity of the Pol and Env protein. Furthermore, regarding the immunogenic activity, the specification does not teach which parts of the proteins Gag, Pol, and Env are immunogenic and therefore, it is not clear which fragments of SEQ ID NO 1, 2 or 3 would encode for proteins that would have immunogenic activity.

Regarding, the limitation of "encoding a derivative," it is noted that the specification does not provide any guidance as to what derivatives of expression products would retain the physiological activity of Gag, Env or Pol. For example, would any fragment of SEQ ID NO 1, 2, 3 would encode a derivative that would have the claimed activity. For example, Smith et al (Accession No AW657531, 05-04-200) disclose a polynucleotide that has 92.7% sequence homology in a region of 548 nucleotides. However, it is not clear whether this would encode a derivative that would have recited activities. Furthermore, Figure 4 lists changes at some nucleotides that result in change in certain amino acids or addition of residues, for example, deletions at 192 or 193 amino acid residue or addition of three residues at residue 206, however, there is not disclosure in the specification whether the Env encoded by polynucleotides with each of these changes alone or cumulatively would have the activity of wild type Env for example, receptor binding and infection. The specification does not teach how would an artisan use Gag, Pol or Env derivatives that lack the activity of the starting proteins. Additionally, the specification does not teach how would an artisan make a polynucleotide which encode derivatives of Gag, Pol, or Env that retain the activity of the starting proteins.

With regard to claim 5, the question is: will every polynucleotide in which 10% of the nucleotide sequences disclosed in SEQ ID NO 2 and 3 have been changed, have the functions

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of Gag, Pol, and Env of porcine virus? Since the sequence encodes three different polynucleotides, based on which part of the sequence of SEQ ID NO 2 or 3 is altered, the encoded protein may not even be a Gag, Pol, or Env, for example, due to frame shift. Furthermore, claimed polynucleotides would encompass variants that encode mutant proteins due to deletion, substitution, and addition in the wild type polynucleotides. It is recognized in the prior art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence, and the functional properties of the different parts of the protein (see second paragraph in Rudinger J in Peptide Hormones. Editor Parsons JA. Pages 1-7, 1976, University Park Press, Baltimore). Rudinger further add, "The significance of particular amino acids and sequences for different aspects of biological activity can not be predicted *a priori* but must be determined from case to case by painstaking experimental study" (see conclusion on page 6). The specification does not teach which changes in the nucleotide sequence of SEQ ID NO 2 or 3 would encode amino acid sequences that would retain the function of the encoded proteins. The specification does not teach how to use a nucleic acid that would have encoded proteins that did not have the function of the wild type protein.

Accordingly, the specification is not enabling for the claimed invention because the specification does not provide sufficient guidance, working examples, and evidence as to how an artisan would have made and used the claimed invention without undue experimentation and therefore, limiting the scope of the claimed invention to an isolated polynucleotide disclosed in SEQ ID NO 1, 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames of 524, 1194, and 656 amino acids each, is proper.

14. Claims 17 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the invention of claims 17 and 19-22 because the specification does not provide sufficient guidance, evidence and working examples as to how an

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artisan would have made and used the claimed invention without undue experimentation as discussed below.

To practice the invention of claims 17, 19-22 would require: that the encompassed primers/probes specifically hybridize to the nucleotides of Figures 1-4 and that these primers/probes do not initiate synthesis of a new strand or hybridize if the polynucleotide is non-PoEv. However, the specification as filed does not disclose what primers or probes would specifically hybridize to the sequence of Figures 1-4 or what would be the sequence of such primers or probes. Sequence comparison results show that there are regions of PoEv which in regions of more than 15 amino acids or more than 20 nucleotides are 100% identical to the sequences of Figures 1-3, for example, the sequence taught by Eiden et al, US 6033905 (see sequence results). The specification does not teach how would an artisan decide whether the sequence of fragments of Eiden et al is not specific to PoEv. Additionally, to find regions of the Figure 1-4, an artisan would have to have the DNA or sequence information of all the non-PoEv sequences in existence to compare each of them with PoEv sequences of Figures 1-4). It is customary to use polynucleotides of 18-20 nucleotides that have 100% sequence identity with a given polynucleotide as a probe or primer for initiating synthesis from the polynucleotide. The specification does not teach what characteristics of the primers, even if they have 100% sequence similarity with the sequences disclosed in Figures 1-4, would result in synthesis from PoEv sequence only. It would be undue experimentation for an artisan to find all the non-PoEv sequences and an artisan would not be able to practice the claimed invention without undue experimentation.

In conclusion, the specification as filed does not provide sufficient guidance, working examples, and evidence for an artisan to make and use the claimed invention without undue experimentation.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claim 22 provides for the use of primer and polynucleotides, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process

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applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 22 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

17. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 5 are indefinite because they recite the term "a physiological activity". The specification does not define as to what would be encompassed by "a physiological activity" since the claim as instantly recited encompasses a broad subject matter.

Claim 2 is indefinite because it recites the term "substantially similar" because "substantially similar" is a relative term and the specification does not provide any guidance as to what would be considered "substantially similar."

Claims 1-5 are indefinite because they recite the term "derivative" in line 4 of each of these claims. Since the term "derivative" is a broad term and a derivative of a given starting material may have totally different characteristic functions compared to the starting material, the metes and bounds of these claims is not clear.

Claims 1-5 are indefinite for following reasons: Lines 1-2 of claims, hereto after referred as the preamble, recite "isolated polynucleotide fragment as shown in Figures 1, 2, 3, or 4" which is closed language equivalent to "isolated polynucleotide fragment consisting of the polynucleotide shown in Figure 1, 2, 3, or 4." Consequently, such polynucleotides can not encode "derivative" and are not complementary as recited in parts (b) and (c) of claim 1.

Claims 1-5 are also indefinite because it is not clear as to how the "preamble" of each of these claims is connected to what is listed in parts (a)-(c). It is not clear whether the parts (a)-(c) of these claims further limit what is recited in the preamble or whether they are in addition to what is recited in the preamble.

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Claims 1-4 are also indefinite because it recites a corresponding RNA sequence of a polynucleotide, although RNA itself is a polynucleotide.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

19. Claims 1-5 parts (b)-(c) are rejected under 35 U.S.C. 102(e) as being anticipated by Eiden et al (US 6033905, 3-7-2000, filing date 4-6-1994).

Eiden et al teach retroviral vectors based on Gibbon Ape Leukemia virus. The sequence disclosed by Eiden et al sequence high similarities with the sequences disclosed in SEQ ID NO 1, 2, 3, 4, 5 etc. in regions of over 20 nucleotides or 16 amino acids (see sequence comparison results) and primers specific to these regions will hybridize to the sequence of SEQ ID NO 1, 2, and 3.

Since Gibbon Ape leukemia virus encodes Gag, Pol, and Env polynucleotides which have similar functions in all the lentiviruses, the invention of claims 1-5, parts (b)-(c) is anticipated by Eiden et al.

20. It is noted that the sequence disclosed in Eiden et al (US 6033905, 3-7-2000, filing date 4-6-1994) meets some limitations of the primers and probes encompassed by claims 17 and 19-22, however, the reference of Eiden et al fails to anticipate the invention of claims 17 and 19-22 for the same reasons that the claims are not enabled by the specification, with respect to non-PoEv sequences.

21. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Ram R. Shukla, Ph.D.

Scott D. Pribe
SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER